IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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| PEGGY DOUGHTERY, individually and as parent and natural guardian of D.J., a minor, | : | |
| Plaintiff, | : | CIVIL ACTION NO. 11-6048 |
| v. | : | |
| C.R. BARD, INC., and DAVOL, INC., | : | |
| Defendants. | : | |

**MEMORANDUM**

YOHN, J. July 18, 2012

Currently before me is defendants' motion to dismiss plaintiff's first amended complaint. As is more thoroughly explained below, several of plaintiff's claims are barred by Pennsylvania law and must be dismissed with prejudice. But I will accede to plaintiff's request to file a second amended complaint in order to attempt to rehabilitate the remaining claims.

## I. FACTUAL BACKGROUND AND PROCEDURAL HISTORY

On September 26, 2011, plaintiff, Peggy Doughtery, filed her original complaint on behalf of herself and her minor child D.J., alleging that D.J. sustained injuries after he was implanted with a PerFix Plug, a medical device manufactured and distributed by defendants for use in the surgical repair of inguinal hernias. Doughtery claims that various defects in the PerFix Plug caused D.J.'s injuries and that defendants were aware of these defects. Doughtery filed her first amended complaint on January 5, 2012, after defendants moved to dismiss the original complaint. Doughtery asserts three claims for strict liability, alleging a manufacturing defect

(count I), a design defect (count II), and a failure to warn (count III). She also asserts a claim for negligence (count IV). Next, Doughtery alleges that defendants breached the implied warranty of merchantability, the implied warranty of fitness for a particular purpose, and an express warranty (count V). And finally, she alleges that defendants violated the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 Pa. Stat. Ann. §§ 201-1 *et seq.* (count VI).

Defendants have filed this motion to dismiss the first amended complaint under Federal Rule of Civil Procedure 12(b)(6).

## II. STANDARD OF REVIEW

In deciding a motion to dismiss under Rule 12(b)(6), courts must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008) (internal quotation marks and citation omitted). But "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements" will not suffice. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). The complaint must contain sufficient factual matter to be plausible on its face. *Id.* "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged"; a sheer possibility that a defendant acted unlawfully is not sufficient. *Id.*

## III. DISCUSSION

In seeking dismissal of Doughtery's first amended complaint, defendants argue, among other things, that the complaint is "impermissibly vague and lacks the factual detail" required under *Iqbal*. (Mem. of Law in Supp. of Defs.' Mot. to Dismiss 1st Am. Compl. ("Defs.' Br." at 2.) I agree and will therefore grant defendants' motion to dismiss. But Doughtery requests that she be granted leave to amend her complaint a second time to add necessary factual details and to correct and strengthen her claims,[1] and I will also grant her request.

Rule 15(a)(2) provides that a court "should freely give leave [to amend a complaint] when justice so requires." Fed. R. Civ. P. 15(a)(2). "Among the grounds that could justify a denial of leave to amend are undue delay, bad faith, dilatory motive, prejudice, and futility." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997). I find no evidence of bad faith, dilatory motive, undue delay, or prejudice here; nor do defendants suggest differently. Defendants contend only that the filing of the second amended complaint attached to the response would be futile because certain of Doughtery's claims are clearly barred by law.

As more fully discussed below, I agree that Doughtery's strict-liability claims, as well as her claim for breach of the implied warranty of merchantability, to the extent that they are based on an alleged design defect or failure to warn, are barred under Pennsylvania law.[2] Doughtery's claim for breach of the implied warranty of fitness for a particular purpose is similarly barred. No amendment would be able to salvage these claims, and thus they must be dismissed with prejudice.[3]

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[1] Doughtery attached her proposed second amended complaint to her brief.

[2] The parties agree that Pennsylvania law applies here.

[3] Doughtery concedes that she cannot maintain her claim under the Unfair Trade Practices

That leaves Doughtery's strict-liability manufacturing-defect claim in count I, her negligence claim in count IV, and her claims for breach of the implied warranty of merchantability (to the extent that it is based on a manufacturing defect) and breach of express warranty in count V. Because these claims, if properly pleaded with sufficient factual allegations, could potentially survive a motion to dismiss, I will allow Doughtery to amend her complaint to allege additional facts and cure the deficiencies in her pleading of these claims, provided that she can do so in compliance with the limits of Rule 11.

I turn now to defendants' arguments that Doughtery's strict-liability and breach-of-warranty claims are barred under Pennsylvania law.

### A. Strict Liability (Counts I–III)

Defendants argue that Doughtery's strict-liability claims fail as a matter of law because manufacturers and sellers of prescription medical devices, such as the PerFix Plug, are not subject to strict liability under Pennsylvania law. Pennsylvania law recognizes three different types of defects that can give rise to a strict-liability claim: a design defect, a manufacturing defect, and a warning defect (i.e., a failure to warn). *See Phillips v. A-Best Prods. Co.*, 665 A.2d 1167, 1170 (Pa. 1995). In this case, Doughtery advances all three theories of strict liability. I agree with defendants that Doughtery's strict-liability claims based on an alleged design defect and an alleged failure to warn are not cognizable under Pennsylvania law. But, contrary to defendants' contention, Doughtery's strict-liability claim based on an alleged manufacturing defect is not clearly barred.

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and Consumer Protection Law, and she has also agreed to strike her inappropriate prayer for attorney fees.

The Pennsylvania Supreme Court has adopted section 402A of the Restatement (Second) of Torts, which imposes strict liability for products sold "in 'a defective condition unreasonably dangerous to the user or consumer.'" *Phillips*, 665 A.2d at 1170 (quoting section 402A). Comment k of this section, however, limits liability for "unavoidably unsafe" products, such as prescription drugs. *See* Restatement (Second) of Torts § 402A cmt. k (1965).[4] The comment recognizes that "[t]here are some products, which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use," and provides that such products, "properly prepared, and accompanied by proper directions and warning, [are] not defective . . . [or] *unreasonably* dangerous." *Id.* Adopting and applying comment k, the Pennsylvania Supreme Court has held that, "assuming proper preparation and warning, a

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[4] Comment k provides in full:

> *Unavoidably unsafe products*. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A cmt. k.

manufacturer of [prescription] drugs is not strictly liable for unfortunate consequences attending the use of otherwise useful and desirable products which are attended with a known but apparently reasonable risk." *Baldino v. Castagna*, 478 A.2d 807, 810 (Pa. 1984).

Defendants contend that comment k "applies equally to prescription medical devices" (Defs.' Br. at 9) and precludes all strict-liability claims, regardless of whether a claim is based on a manufacturing defect, a design defect, or a failure to warn (Reply Br. in Supp. of Defs.' Mot. to Dismiss 1st Am. Compl. at 3).

The first question thus is whether comment k applies to prescription medical devices such as the PerFix Plug. Although the Pennsylvania Supreme Court has addressed the application of comment k only in the context of prescription drugs, the Superior Court has applied comment k to prescription medical devices, "find[ing] no reason why the same rational[e] applicable to prescription drugs may not be applied to medical devices." *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. Ct. 2006). Similarly, numerous courts in this district have predicted that the Supreme Court would extend comment k to prescription medical devices. *See Esposito v. I-Flow Corp.*, No. 10-3883, 2011 WL 5041374, at *4 (E.D. Pa. Oct. 24, 2011); *Geesey v. Stryker Corp.*, No. 09-2988, 2010 WL 3069630, at *3–4 (E.D. Pa. Aug. 4, 2010); *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 750 (E.D. Pa. 2007); *Davenport v. Medtronic, Inc.*, 302 F. Supp. 2d 419, 441–42 (E.D. Pa. 2004); *Murray v. Synthes (U.S.A.), Inc.*, No. 95-7796, 1999 WL 672937, at *7 (E.D. Pa. Aug. 23, 1999); *Taylor v. Danek Medical, Inc.*, No. 95-7232, 1998 WL 962062, at*7 (E.D. Pa. Dec. 29, 1998); *see also Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 747 (W.D. Pa. 2004) (agreeing "with the district courts in the Eastern District of Pennsylvania that the same considerations exempting prescription drugs from the ambit of § 402A equally apply to prescription medical devices"). I agree with the reasoning of these courts. Moreover, Doughtery

apparently does not dispute that comment k applies to prescription medical devices and offers no argument for excepting the PerFix Plug from the scope of comment k.[5]

Having concluded that comment k applies to the PerFix Plug, I next address whether comment k precludes Doughtery's strict-liability claims. As previously mentioned, Doughtery alleges a design defect, a manufacturing defect, and a failure to warn. I discuss each claim in turn.

Courts agree that, by its terms, comment k excepts "unavoidably unsafe" products from strict liability for design defects. *See, e.g.*, *Brown*, 751 P.2d at 477; *Toner*, 732 P.2d at 305; *Savina*, 795 P.2d at 924; *Castrignano*, 546 A.2d at 780; *Grundberg*, 813 P.2d at 92. Thus the Pennsylvania Superior Court has explained that "[w]ith our Supreme Court's adoption of comment k, a design defect claim for strict liability is not cognizable under Pennsylvania law when it is asserted against a manufacturer of prescription drugs." *Lance v. Wyeth*, 4 A.3d 160, 165 (Pa. Super. Ct. 2010), *appeal granted on other grounds by* 15 A.3d 429 (Pa. 2011).

Pointing out that comment k's exemption from strict liability is conditioned on the requirement that the product be "properly prepared and accompanied by proper directions and warnings," Restatement (Second) of Torts § 402A, cmt. k, Doughtery seems to suggest that, even

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[5] Many courts apply comment k on a case-by-case basis and analyze each product, whether a prescription drug or a prescription medical device, to determine whether it is within the scope of comment k. *See, e.g.*, *Toner v. Lederle Labs.*, 732 P.2d 297, 305–08 (Idaho 1987); *Savina v. Sterling Drug, Inc.*, 795 P.2d 915, 924–26 (Kan. 1990); *Feldman v. Lederle Labs.*, 479 A.2d 374, 383 (N.J. 1984); *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 781 (R.I. 1988). Some courts, however, treat all prescription drugs and devices as "unavoidably unsafe" and within the scope of comment k as a matter of law. *See Transue v. Aesthetech Corp.*, 341 F.3d 911, 915–17 (9th Cir. 2003) (applying Washington law); *Brown v. Superior Court*, 751 P.2d 470, 477 (Cal. 1988); *Grundberg v. Upjohn Co.*, 813 P.2d 89, 93–95 (Utah 1991). The Pennsylvania Supreme Court has not expressly addressed these different approaches but has applied comment k to prescription drugs without any individualized analysis. *See Hahn v. Richter*, 673 A.2d 888 (Pa. 1996); *Baldino*, 478 A.2d 807.

if her design-defect claim fails, she may still maintain strict-liability claims based on an alleged manufacturing defect and on defendants' alleged failure to provide proper warnings.[6]

But with respect to failure-to-warn claims, the Pennsylvania Supreme Court has made it clear that strict liability does not apply and that "negligence is the only recognized basis for recovery." *Hahn v. Richter*, 673 A.2d 888, 889 (Pa. 1996). As the court explained, "where the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer's negligence, is the only recognized basis of liability." *Id.* at 891.

The Pennsylvania Supreme Court has not, however, addressed the "properly prepared" condition cited by Doughtery or otherwise discussed whether comment k's exemption from strict liability extends to manufacturing-defect claims. Nonetheless, several district courts have read *Hahn* broadly to preclude all strict liability claims. *See Gross v. Stryker Corp.*, No. 11-1229, __ F. Supp. 2d ___, 2012 WL 876719, at *8–9 (W.D. Pa. Mar. 14, 2012); *Horsmon v. Zimmer Holdings, Inc.*, No. 11-1050, 2011 WL 5509420, at * 2 (W.D. Pa. Nov. 10, 2011); *Soufflas*, 474 F. Supp. 2d at 748–50; *Parkinson*, 315 F. Supp. 2d at 747–48; *Davenport*, 302 F. Supp. 2d at

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[6] In her proposed second amended complaint, which she has attached to her brief opposing defendants' motion to dismiss, Doughtery combines the design-defect and manufacturing-defect theories of strict liability in a single count. Those two theories are distinct, however, and, as discussed above, comment k clearly precludes strict liability based on a design defect.

Interestingly, Doughtery recognizes this distinction in connection with her negligence claims—citing *Leibowitz v. Ortho Pharmaceutical Corp.*, 307 A.2d 449 (Pa. Super. Ct. 1973), she "concedes that there are only two potential negligence causes of action under Pennsylvania law: 1) negligent failure to warn; and 2) negligent preparation of a product." (Pl.'s Resp. to Defs.' Mot. to Dismiss Pl.'s 1st Am. Compl. at 5.) I need not decide here whether that is an accurate characterization of Pennsylvania law. I note, however, that the Pennsylvania Superior Court recently held that a negligent design claim is a valid cause of action. *See Lance*, 4 A.3d at 165–66. That case is currently on appeal to the Pennsylvania Supreme Court.

441–42. *But see Schiff v. Hurwitz*, No. 12-0264, 2012 WL 1828035, at *5 (W.D. Pa. May 18, 2012) (holding that plaintiff had adequately pleaded strict-liability claim where it was based on more than a failure to warn). Few of these courts, however, have addressed the "properly prepared" requirement in comment k or otherwise distinguished among design-defect, manufacturing-defect, and failure-to-warn claims in concluding that strict-liability claims against manufacturers of prescription drugs and devices are not cognizable under Pennsylvania law.[7]

More recently, however, the Pennsylvania Superior Court read *Hahn* and its predecessors more narrowly and recognized a strict-liability claim based on an alleged manufacturing defect as a viable cause of action against a manufacturer of prescription drugs. *See Lance*, 4 A.3d at 164–65. The court explained that, as a result of the Pennsylvania Supreme Court's adoption of comment k, a plaintiff may not assert a strict-liability design-defect claim against a manufacturer of prescription drugs. *See id.* at 165. But, the court asserted, a plaintiff may still assert a strict-liability claim based on either a manufacturing defect or a failure to warn. *See id.* at 164–65. Although the court then explained that, under *Hahn*, such a failure-to-warn claim would be "analyzed and adjudicated in accordance with the negligence standard contained in the Restatement (Second) of Torts § 388," the court did not suggest that a manufacturing-defect

[7] In *Parkinson*, the court did consider what it referred to as the "'properly prepared' caveat," 315 F. Supp. 2d at 748, but concluded that the caveat was to be "evaluated under negligence, not strict liability, principles," *id.* at 747. Recognizing that other jurisdictions have permitted strict-liability manufacturing-defect and failure-to-warn claims under comment k's caveats, the court nonetheless concluded that, under Pennsylvania law, "it must be assumed that, as with inadequate warnings, the only recognized basis of liability for an improperly prepared product likewise is negligence." *Id.* at 748. In reaching this conclusion, the court cited *Hahn*, *Baldino*, and *Incollingo v. Ewing*, 282 A.2d 206 (Pa. 1971), and asserted that "the Pennsylvania Supreme Court unambiguously has held that § 402A strict liability does not apply in any way to prescription drugs." *Parkinson*, 315 F. Supp. 2d at 748 & n.6. As I discuss in more detail below, however, I see nothing in those cases that unambiguously precludes all strict-liability claims against a prescription-drug manufacturer.

claim would also be governed by a negligence standard.[8] *See id.* at 165.

Like the Superior Court, I do not read *Hahn*, *Baldino*, or *Incollingo* as barring strict-liability manufacturing-defect claims against a manufacturer of prescription drugs or devices.

First, I see nothing in those cases that unambiguously precludes all strict-liability claims against a prescription-drug manufacturer.[9]

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[8] I note, however, that the plaintiff in *Lance* did not allege a manufacturing defect, *see Lance*, 4 A.3d at 165, and thus court had no need to address the viability of such a claim or the proper standard to be applied.

[9] In *Incollingo*, the plaintiff asserted a claim against the manufacturer of a prescription drug for negligent failure to warn. 282 A.2d at 218–19. Nonetheless, in determining the proper standard for assessing whether the manufacturer's warnings were adequate, the court started its analysis with section 402A of the Restatement (Second) of Torts, which imposes strict liability for products sold "in a defective condition unreasonably dangerous to the user or consumer." Restatement (Second) of Torts § 402A. The court first noted that "[c]omment h . . . makes it clear that a product, as to which adequate warning of danger involved in its use is required, sold without such warning is in a 'defective condition.'" *Incollingo*, 282 A.2d at 219. The court then discussed comment j, which addresses the duty to warn, and quoted some of its language: "'Where warning is given, the seller may reasonably assume that it will be read and heeded; and the product bearing such a warning, which is safe for use if it is followed, is not in defective condition nor is it unreasonably dangerous.'" *Id.* (quoting Restatement (Second) of Torts § 402A cmt. j)). Referring to comment k, the court explained that "[t]he Restatement reaches the same conclusion" with respect to unavoidably unsafe products—"'The seller of such products,' concludes this comment, 'again with the qualification that they are properly prepared and marketed *and proper warning is given*, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product attended with a known but apparently reasonable risk.'" *Id.* at 219–20. The court asserted that the prescription drug at issue was "a drug in this category," *id.* at 220, and in a footnote simply stated that "[s]ince the strict liability rule of § 402A is not applicable, the standard of care required is that set forth in § 388 of the Restatement dealing with the liability of a supplier of a chattel known to be dangerous for its intended use," *id.* at 220 n.8. The court did not clarify whether its conclusion that the "strict liability rule of § 402A is not applicable" applied only to the alleged failure to warn or whether it applied more broadly to any claim against a manufacturer of a prescription drug. But given that the only issue before the court was an alleged failure to warn and given that the court did not say anything about manufacturing defects, I think that it is reasonable to read the court's conclusion as applying only to failure-to-warn claims.

Similarly, in *Baldino*, the plaintiff asserted a claim for negligent failure to warn. 478 A.2d at 810. The court relied largely on *Incollingo*, but did not clarify the scope of its prior opinion:

Second, the fact that the Pennsylvania Supreme Court decided to apply a negligence standard to failure-to-warn claims does not necessarily mean that the court would similarly adopt a negligence standard for manufacturing-defect claims. As the court explained in *Hahn*, in reaching its conclusion in *Incollingo* and *Baldino* that negligence is the only basis for recovery for an alleged failure to warn, it relied in part on comment j, which "provides that a seller must warn of risks, not generally known and recognized, of which he has or reasonably should have knowledge," and further provides "that it can be assumed that where warnings are given they will be read and heeded," *Hahn*, 673 A.2d at 890—a standard that, as some courts have recognized, sounds in negligence, *see Brown*, 751 P.2d at 476 & n.4.[10] Indeed, although many courts assert that comment k permits strict-liability claims based on a failure to warn, like the Pennsylvania Supreme Court they typically employ a negligence standard for such claims. *See, e.g.*, *Toner*, 732

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> In *Incollingo* we held that, assuming proper preparation and warning, a manufacturer of drugs is not strictly liable for unfortunate consequences attending the use of otherwise useful and desirable products which are attended with a known but apparently reasonable risk. *Id.* at 288, 282 A.2d at 221. Rather, such a manufacturer is liable only if he fails to exercise reasonable care to inform those for whose use the article is supplied of the facts which make it likely to be dangerous.

*Id.*

Finally, at issue in *Hahn* was whether the trial court had erred in refusing to instruct the jury on strict liability, and instead issuing negligence instructions, with respect to the plaintiff's failure-to-warn claims. 673 A.2d at 889. The court relied largely on *Incollingo* and *Baldino* and addressed comment k only in the context of an alleged failure to warn. *See id.* at 889–91.

[10] Although the California Supreme Court has incorporated this knowledge requirement as a component of strict liability and has recognized that this requirement "infuses some negligence concepts into strict liability cases," *Carlin v. Superior Court*, 920 P.2d 1347, 1350 (Cal. 1996), the court has maintained a distinction between strict liability and negligence and has applied strict liability in failure-to-warn cases, *id.* at 1351–54. As the court explained: "Strict liability is not concerned with the standard of due care or the reasonableness of a manufacturer's conduct. The rules of strict liability require a plaintiff to prove only that the defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution." *Id.* at 1351.

P.2d at 305 & n.7 (asserting that comment k does not except unavoidably unsafe products from liability where the plaintiff alleges an inadequate warning, but noting that generally there is "little difference in the requirements and analysis of the duty to warn under either a negligence or strict liability theory" (internal quotation marks omitted)); *Savina*, 795 P.2d at 928 (asserting that "in all warning cases—even if the plaintiff or the court claims to analyze failure to warn or inadequacy of warning in the context of a strict products liability claim—the tests actually applied condition imposition of liability on the defendant's having actually or constructively known of the risk that triggers the warning," and that "the adequacy of a warning is . . . judged under a reasonableness standard" (internal quotation marks omitted)); *Martin v. Hacker*, 628 N.E.2d 1308, 1311 (N.Y. 1993) ("Where liability is predicated on a failure to warn, New York views negligence and strict liability claims as equivalent."). As some commentators have noted, "courts increasingly acknowledge that the basis of liability is virtually, or completely, equivalent in negligence and strict liability in tort, in both warnings cases and cases of design." 1 David G. Owen, M. Stuart Madden & Mary J. Davis, *Madden & Owen on Products Liability* § 5:9, at 326 (3d ed. 2000) (footnotes omitted). The concern is that "if a manufacturer could not count on limiting its liability to risks that were known or knowable at the time of manufacture or distribution, it would be discouraged from developing new and improved products for fear that later significant advances in scientific knowledge would increase its liability." *Carlin*, 920 P.2d at 1350.

But similar concerns about strict liability do not apply in the context of manufacturing-defect claims. *See* Victor E. Schwartz & Phil Goldberg, *A Prescription for Drug Liability and Regulation*, 58 Okla. L. Rev. 135, 152 (2005) ("As with other products, strict liability in the manufacturing of prescription drugs creates appropriate incentives for companies to ensure good

quality control and that their products are made as intended."); Restatement (Third) of Torts: Products Liability § 6 cmt. c (1998) ("Limitations on the liability for prescription drug and medical-device designs do not support treating drug and medical-device manufacturers differently from commercial sellers of other products with respect to manufacturing defects.").[11] Courts and commentators thus generally agree that comment k's immunity from strict liability does not extend to manufacturing defects. *See, e.g.*, *Transue*, 341 F.3d at 918–19 (collecting cases and concluding that, under Washington law, manufacturers of "unavoidably unsafe" products remain subject to strict liability for manufacturing defects); *Brown*, 751 P.2d at 483 n.12 (explaining that even under comment k, manufacturers of prescription drugs remain subject to strict liability for manufacturing defects); *Toner*, 732 P.2d at 305 ("Comment k intends to shield from strict liability products which cannot be designed more safely; however, if such products are mismanufactured . . . , then the seller may be liable even if the plaintiff cannot establish the seller's negligence"); *Savina*, 795 P.2d at 924 (explaining that comment k "cannot apply to products that contain a manufacturing flaw"); *Grundberg*, 813 P.2d at 92 ("[C]omment k's immunity from strict liability does not extend to strict liability claims based on a manufacturing flaw"); Restatement (Third) of Torts: Product Liability § 6 cmt. c ("Courts have traditionally subjected manufacturers of prescription products to liability for harm caused by manufacturing defects.").

I thus conclude that, although Pennsylvania law does not recognize a strict-liability claim based on a design defect or a failure to warn as a viable cause of action against a manufacturer of prescription drugs or devices, Pennsylvania law does not preclude a strict-liability claim based on

[11] The Pennsylvania Supreme Court has not adopted this section of the new Restatement.

a manufacturing defect.

Because Doughtery's strict-liability claims based on a design defect and a failure-to-warn (counts II and III) are not cognizable under Pennsylvania law, any amendment to these claims would be futile. But because I conclude that her manufacturing-defect claim (count I) is not barred under Pennsylvania law, I will allow Doughtery to file an amended complaint to allege additional facts and cure the deficiencies in her pleading of this claim.

### B. Breach of Warranty (Count V)

In count V of the first amended complaint, Doughtery asserts claims for breach of the implied warranties of merchantability and of fitness for a particular purpose, as well as breach of express warranty. Defendants argue that Pennsylvania law does not recognize such claims against manufacturers of prescription drugs and medical devices. I agree that Doughtery's claim for breach of the implied warranty of fitness for a particular purpose is precluded here. Similarly, to the extent that Doughtery's claim for breach of the implied warranty of merchantability is based on an alleged design defect or failure to warn, it is not cognizable. But, contrary to defendants' contentions, to the extent that the claim is based on an alleged manufacturing defect, it is not barred under Pennsylvania law. Nor is Doughtery's claim for breach of express warranty precluded.

#### 1. Breach of Implied Warranty of Merchantability

The implied warranty of merchantability arises by operation of law, *see* 13 Pa. Cons. Stat. § 2314, and "serve[s] to protect buyers from loss where goods purchased are below commercial standards," *Turney Media Fuel, Inc. v. Toll Bros., Inc.*, 725 A.2d 836, 840 (Pa. Super. Ct. 1999).

Under section 2314, "a warranty that the goods shall be merchantable is implied in a

contract for their sale if the seller is a merchant with respect to goods of that kind." 13 Pa. Cons. Stat. § 2314(a).[12] To be "merchantable," goods must "have an inherent soundness which makes them suitable for the purpose for which they are designed, . . . be free from significant defects, . . . perform in the way that goods of that kind should perform, and . . . be of reasonable quality within expected variations and for the ordinary purpose for which they are used." *Gall v. Allegheny County Health Dep't*, 555 A.2d 786, 789–90 (Pa. 1989) (citations omitted).

As defendants point out, several federal district courts in Pennsylvania have concluded that comment k precludes claims for breach of the implied warranty of merchantability against manufacturers of prescription drugs and devices. *See Kester v. Zimmer Holdings, Inc.*, No. 10-0523, 2010 WL 2696467, at *11 (W.D. Pa. June 16, 2010); *Soufflas*, 474 F. Supp. 2d at 751–52; *Parkinson*, 315 F. Supp. 2d at 752–53; *Davenport*, 302 F. Supp. 2d at 442; *Murray*, 1999 WL

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[12] Section 2314 provides, in relevant part:

> (a) Sale by merchant.—Unless excluded or modified (section 2316), a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind. Under this section the serving for value of food or drink to be consumed either on the premises or elsewhere is a sale.
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> (b) Merchantability standards for goods.—Goods to be merchantable must be at least such as:
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> (1) pass without objection in the trade under the contract description;
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> (2) in the case of fungible goods, are of fair average quality within the description;
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> (3) are fit for the ordinary purposes for which such goods are used;
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> (4) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved;
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> (5) are adequately contained, packaged, and labeled as the agreement may require; and
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> (6) conform to the promises or affirmations of fact made on the container or label if any.

13 Pa. Cons. Stat. § 2314.

672937, at *9; *Taylor*, 1998 WL 962062, at *13–14. In predicting that the Pennsylvania Supreme Court would decline to recognize such implied-warranty claims, these courts relied largely on *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, in which the Pennsylvania Superior Court, addressing the question whether a pharmacist who properly fills a prescription may be liable for breach of the implied warranty of merchantability, concluded that "the very nature of prescription drugs themselves precludes the imposition of a warranty of fitness for 'ordinary purposes,' as each individual for whom they are prescribed is a unique organism who must be examined by a physician who is aware of the nature of the patient's condition as well as the medical history of the patient." 523 A.2d 374, 377 (Pa. Super. Ct. 1987) (discussing comment k).

I agree with these courts insofar as they held that comment k precludes implied-warranty claims against manufacturers of prescription drugs and devices to the same extent that it precludes strict-liability claims against such manufacturers.

As many courts have recognized, the theories of strict liability and breach of the implied warranty of merchantability "are parallel theories of recovery, one in contract and the other in tort." *Castrignano*, 546 A.2d at 783; *accord Williams v. West Penn Power Co.*, 467 A.2d 811, 815 n.16 (Pa. 1983) (noting that the causes of action for strict liability under section 402A of the Restatement (Second) of Torts and for breach of the implied warranty of merchantability under the Uniform Commercial Code "are co-extensive" but "not identical"). "[A] breach of implied warranty theory is a form of strict liability without the necessity of proving negligence or fault on the part of the defendant." *State Farm Fire & Cas. Co. v. Miller Electric Co.*, 562 N.E.2d 589, 595 (Ill. App. Ct. 1990); *accord Kassab v. Central Soya*, 246 A.2d 848, 853 (Pa. 1968) ("[O]nce a breach of warranty has been shown, the defendant's liability, assuming of course the presence of proximate cause and damages, is absolute. Lack of negligence on the seller's part is no

defense."), *overruled on other grounds by AM/PM Franchise Ass'n v. Atlantic Richfield Co.*, 584 A.2d 915 (Pa. 1990). It would thus be inconsistent to exempt a manufacturer of prescription medical devices from strict liability under comment k and apply a negligence standard to determine liability for a design defect or a failure to warn, but allow a plaintiff to recover for the same alleged defect under a theory of breach of the implied warranty of merchantability. Accordingly, to the extent that Doughtery's implied-warranty claim is based on a design defect or a failure to warn, I conclude that it is not cognizable under Pennsylvania law and must be dismissed with prejudice.

But, because I have concluded that Pennsylvania law does not preclude a strict-liability claim based on a manufacturing defect, I see no basis for declining to recognize a claim for breach of the implied warranty of merchantability where it is based on a manufacturing defect. Accordingly, to the extent that Doughtery bases her implied-warranty claim on a manufacturing defect, I will grant Doughtery's request that she be allowed to file an amended complaint to allege additional facts and cure the deficiencies in her pleading of this claim.

### 2. Breach of the Implied Warranty of Fitness for a Particular Purpose

Defendants also contend that Doughtery's claim for breach of the implied warranty of fitness for a particular purpose is barred under Pennsylvania law. I agree.

Like the implied warranty of merchantability, the implied warranty of fitness for a particular purpose also arises by operation of law. *See* 13 Pa. Cons. Stat. § 2315.[13] But whereas

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[13] Section 2315 provides:

Where the seller at the time of contracting has reason to know:

(1) any particular purpose for which the goods are required; and

the implied warranty of merchantability "is based on the seller's implicit representation that the product will safely and effectively perform the *normal* functions for which that type of product is ordinarily bought and sold," the implied warranty of fitness for a particular purpose "is an implied promise by the seller that the product sold will meet the buyer's *particular* needs." 1 *Madden & Owen on Products Liability* § 4:8, at 154. It is "based upon a special reliance by the buyer on the seller to provide goods that will perform a specific use envisaged and communicated by the buyer." *Gall*, 555 A.2d at 790. A claim for breach of the implied warranty of fitness for a particular purpose does not require that a product be defective; rather, this warranty "may be breached when a product properly made and merchantable is simply the wrong one for the buyer's particular use." 1 *Madden Owen on Products Liability* § 4:8, at 162; *see also id.* (explaining that "the concepts of merchantability and defectiveness are unrelated to claims for breach of the implied warranty of fitness for a particular purpose").

Here, however, Doughtery's claim that defendants breached the implied warranty of fitness for a particular purpose is essentially a claim that the PerFix Plug was not safe for the particular purpose for which it was to be used and that defendants, knowing that it was to be used for that purpose and that D.J.'s doctors were relying on defendants' judgment or skill to select or furnish a suitable device, supplied the PerFix Plug without warning of its risks, including the risk that it would not be suitable for that particular purpose. But where, as here, a product is considered "unavoidably unsafe," it would be inconsistent with the policy underlying comment k

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> (2) that the buyer is relying on the skill or judgment of the seller to select or furnish suitable goods;
>
> there is . . . an implied warranty that the goods shall be fit for such purpose.

13 Pa. Cons. Stat. § 2315.

to find an *implied* promise by the manufacturer that the product is suitable for a particular purpose and to subject the manufacturer to strict liability for a personal injury resulting from a breach of that implied promise. The same policy considerations that except manufacturers of prescription drugs and devices from strict liability for design and warning defects apply here as well and counsel against imposing liability under an implied-warranty theory. I thus conclude that Doughtery's claim for breach of the implied warranty of fitness for a particular purpose must fail as a matter of law.

**3. Breach of Express Warranty**

Finally, defendants contend that it is "clear that express warranty claims are not cognizable in either . . . the prescription pharmaceutical or prescription medical device products liability context." (Defs.' Br. at 15.) I disagree.

As a preliminary matter, I note that, contrary to defendants' suggestion, federal courts in Pennsylvania are split on this issue. Some courts have recognized an express-warranty claim as a viable cause of action against manufacturers of prescription drugs and devices, albeit without discussing whether comment k precludes such a claim. *See, e.g.*, *Kee v. Zimmer, Inc.*, No. 11-7789, 2012 WL 1758618, at *3 (E.D. Pa. May 17, 2012); *Horsmon*, 2011 WL 5509420, at *3–4; *Esposito*, 2011 WL 5041374, at *6; *Kester*, 2010 WL 2696467, at *10–11; *Parkinson*, 315 F. Supp. 2d at 751–52; *Davenport*, 302 F. Supp. 2d at 440–41. Other courts, however, have concluded that Pennsylvania law precludes such an express-warranty claim. *See, e.g.*, *Aaron v. Wyeth*, No. 07-0927, 2010 WL 653984, at *11 (W.D. Pa. Feb. 19, 2010); *Kline v. Pfizer, Inc.*, No. 08-3238, 2008 WL 4787577, at *3 (E.D. Pa. Oct. 31, 2008); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006), *aff'd on other grounds*, 521 F.3d 253 (3d Cir. 2008), *vacated*

129 S. Ct. 1578 (2009).

I conclude that Pennsylvania law does not preclude express-warranty claims against manufacturers of prescription drugs and devices.

Unlike an implied warranty, which arises by operation of law, an express warranty is based on express representations or promises made by the seller. *See* 13 Pa. Cons. Stat. § 2313.[14] A claim for breach of express warranty thus sounds more in contract than in tort. While the reasoning of comment k may prevent certain warranties or promises from being *implied* by law, I see no basis for declining to enforce a contractual promise expressly and voluntarily made by a manufacturer of prescription drugs or devices.

Some courts, however, have read *Hahn* broadly to bar "all claims [against manufacturers of prescription drugs and devices] that do not rest on a theory of negligence." *Aaron*, 2010 WL 653984, at *11. I disagree with their reading of the case. In *Hahn*, the Pennsylvania Supreme

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[14] Section 2313 provides:

> (a) General rule.—Express warranties by the seller are created as follows:
>
> (1) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
>
> (2) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
>
> (3) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.
>
> (b) Formal words or specific intent unnecessary.—It is not necessary to the creation of an express warranty that the seller use formal words such as "warrant" or "guarantee" or that he have a specific intention to make a warranty, but an affirmation merely of the value of the goods or a statement purporting to be merely the opinion of the seller or commendation of the goods does not create a warranty.

13 Pa. Cons. Stat. § 2313.

Court was presented only with a failure-to-warn claim, and the court explained that "where the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer's negligence, is the only recognized basis of liability." 673 A.2d at 891. The court did not consider other theories of liability such as breach of express warranty, and, given the contractual nature of an express-warranty claim, I see nothing in the court's opinion that precludes such a claim.

I thus conclude that Pennsylvania law does not preclude express-warranty claims against manufacturers of prescription drugs and devices. Accordingly, I will allow Doughtery to amend her complaint to allege additional facts and cure the deficiencies in her pleading of this claim.[15]

## IV. CONCLUSION

For the reasons set forth above, I will grant defendants' motion to dismiss Doughtery's first amended complaint. I will dismiss with prejudice Doughtery's claims for strict liability based on a design defect (count II) and a failure to warn (count III); her claims (in count V) for breach of the implied warranty of merchantability (but only insofar as it is based on an alleged design defect or failure to warn) and breach of the implied warranty of fitness for a particular purpose; and her claim under the Unfair Trade Practices and Consumer Protection Law (count VI). But as to the remaining claims in counts I, IV, and V, I will allow Doughtery to file a second amended complaint to allege additional facts and cure the deficiencies in her pleading of these claims, provided that she can do so in compliance with the limits of Rule 11.

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[15] I caution Doughtery that she must allege sufficient facts to support an inference that an express warranty was created, including the specific source of the alleged warranty (e.g., a publication or package insert) and the specific statements made, *see, e.g.*, *Kester*, 2010 WL 2696467, at *10–11—something that she has not done in either her first amended complaint or her proposed second amended complaint.

The infirmities in Doughtery's first two complaints were due, at least in part, to her counsel's apparent unfamiliarity with the applicable law. I caution Doughtery and her counsel to carefully review the relevant law before drafting and filing her second amended complaint. I am unlikely to allow a third amended complaint should her second amended complaint fail to plead adequate factual allegations or legally proper claims for relief.

An appropriate order accompanies this memorandum.